

FEB 24 2004

K040249
p1/2

510(k) Summary

SUBMITTED ON BEHALF OF:

Company Name: Leonhard Lang GmbH
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by: Elaine Duncan, MS.M.E., RAC
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CONTACT PERSON: Elaine Duncan

DATE PREPARED: January 30, 2004

Trade Name: Skintact® ECG Electrode
Common Name: Disposable ECG Electrodes
Classification Name: Electrocardiograph (ECG) electrode

SUBSTANTIALLY EQUIVALENT TO: Skintact® radiolucent and MRI-compatible ECG Electrodes Skintact® radiolucent and MRI-compatible ECG Electrodes are substantially equivalent to the Skintact® ECG Electrodes (the manufacturer's predicate devices) and equivalent to predicate ECG electrodes cleared under K971444 and K991105.

DESCRIPTION of the DEVICE: Skintact® ECG Electrodes (*and as also to be offered for sale under various private label tradenames*) will now also be offered radiolucent and MRI-compatible. Just like the predicate electrodes, radiolucent and MRI-compatible ECG electrodes are self-adhesive, non-sterile, single-use disposable snap electrodes. The radiolucent and MRI-compatible ECG electrodes are identical in size, shape and configuration to the Skintact ECG electrodes currently marketed by Leonhard Lang, GmbH.

The Skintact® radiolucent and MRI-compatible ECG Electrodes are composed of the same materials as the predicate devices except the snap, which is made of carbon. The carbon snap guarantees an unimpaired performance during the shelf-life of the product. All electrodes include an carbon ABS sensor element coated with silver. The silver layer is either completely or partially (in the areas in contact with the conductive gel) covered with a silver chloride layer.

INDICATIONS FOR USE:

Skintact® radiolucent and MRI-compatible ECG electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording. Skintact radiolucent and MRI-compatible ECG electrodes are single-use, non-sterile, disposable and are to be used on intact (uninjured) skin. (NO CHANGE to ORIGINAL INDICATION for USE.)

SUMMARY of TESTING:

All materials used in this new device have been cleared in the following 510(k)s:

K 982521 Skintact® ECG Electrodes, S&W ECG Electrodes
K 023503 Leonhard Lang Skintact® ECG Electrodes with solid adhesive gel
K 024264 Leonhard Lang Skintact® ECG Electrodes with KS 01 solid wet gel
K 024247 Leonhard Lang Skintact® ECG Electrodes with KL 02 liquid gel

Biocompatibility testing of all materials cleared by 510(k)s confirms the materials are biocompatible and does not introduce any risks. The following testing of the different materials showed no adverse results: Cytotoxicity; Skin Irritation; Sensitization.

The ANSI/AAMI EC 12:2000 "Disposable ECG electrodes" was used to define the requirements for Skintact ECG Electrodes. All electrical tests are according to ANSI/AAMI EC 12:2000. A certification to conformance EC12:2000 with this standard has been provided. The testing conducted was: AC impedance; DC offset voltage; Defibrillation overload recovery; Combined offset instability and internal noise; Bias current tolerance.

The shelf life of radiolucent and MRI-compatible electrodes – new device - was tested in real-time aging. All Skintact® ECG Electrodes (and as also to be offered for sale under various private label tradenames) are packaged in water-vapour-proofed, heat-sealed, non-transparent, aluminized pouches. Leonhard Lang has about 20 years of experience with this packaging and has met requirements for the 24 months shelf-life. No differences were required for packaging the Skintact® radiolucent and MRI-compatible ECG electrodes compared to the predicate devices.

The results of these tests confirm that the shelf-life of Leonhard Lang Skintact radiolucent and MRI-compatible ECG Electrodes is well inside the limits defined in ANSI/AAMI EC12-2000. Thus the conclusion that the electrical performance of the electrodes will stay within the limits during their shelf-life of 24 months. The comparison with the predicate devices and the data from radiolucent and MRI-compatible electrodes shows similar results. The difference is negligible in the limits defined in ANSI/AAMI EC12-2000. Therefore electrical performance of the predicate devices and Skintact® radiolucent and MRI-compatible ECG electrodes is equivalent.

Clinical data: Repeating EC12:2000 testing confirms equivalent data and the change in snap can not affect adhesive performance. So material change -- in this case the change in snap -- does not affect wear tests and adhesive performance. Therefore these tests were not repeated. The potential effect of material change to the conducting signal was evaluated by repeating the trace testing on the carbon electrodes with different approved gels and determined that the carbon electrodes perform the same. Comparing the ECG traces between carbon electrodes with different approved gels and predicate device ECG electrodes demonstrate that carbon electrodes are equivalent to the predicate device ECG electrodes.

Radiolucency:

Radiolucency was tested according standard ASTM F640-79 "Standard Test Methods for Radiopacity of Plastics for Medical Use". Reference: "Radiopacity of ECG-Electrodes by Leonhard Lang GmbH – A study by Dr.Recheis Wolfgang, Dr.Verius Michael, Dr.Huttary Ralf, Mag.Torbica Pavle".

MRI-Compatibility:

MRI compatibility was tested according ASTM F 2052-00 "Standard Test Method for Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment", ASTM F 2182-02a "Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging", ASTM F 2119-01 "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants". Reference: "MR-compatibility of ECG-Electrodes by Leonhard Lang GmbH – A study by Dr.Recheis Wolfgang, Dr.Verius Michael, Dr.Huttary Ralf, Mag.Torbica Pavle".



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2004

Leonard Lang GmbH
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082-0560

Re: K040249

Trade Name: Skintack ECG Electrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrograph Electrode
Regulatory Class: II (two)
Product Code: DRX
Dated: January 30, 2004
Received: February 03, 2004

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

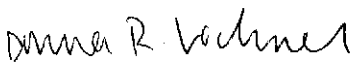
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Ms. Elaine Duncan, M.S.M.E., RAC

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K040249**

Device Name: **Skintact[®] radiolucent and MRI-Compatible ECG Electrodes**

Indications For Use:

Skintact radiolucent and MRI-compatible ECG electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording.

Skintact radiolucent and MRI-compatible ECG electrodes are single use, non-sterile and disposable and are to be used on intact (uninjured) skin.

Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Beckner
Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number *K040249*

Page 1 of *1*